Remarks

Applicant acknowledges with appreciation the statement in the Office Action that Claims

1 and 2 are allowable.

Claims 3 and 4 were rejected under 35 U.S.C. § 112, first paragraph on the grounds

that the specification's disclosure of *in vitro* treatment of cancer does not provide enablement for

in vivo treatment of cancer. This rejection has been carefully considered, and is most respectfully

traversed for the reasons set forth below. Applicant has herein added new claim 5, which recites

the method of claim 3 wherein the neoplastic disease is further defined, and new claim 6, which

recites the method of claim 4 wherein the cancer to be treated is further defined.

Applicant traverses the rejection of claims 3 and 4, and maintains that they are

sufficiently enabled by the disclosure in the specification. The Office Action fails to set forth

evidence that there is no correlation between the *in vitro* test results described in the specification

and *in vivo* effects of the compounds at issue, as is required according to MPEP § 2164.02. As

also noted in MPEP § 2164.02, the Federal Circuit in the case of *In re Brana*, 51 F. 3d 1560,

1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) reversed the USPTO's decision based on the

USPTO's finding that *in vitro* data did not support *in vivo* applications.

Those of ordinary skill in the relevant art would find a teaching of a particular

compound's *in vivo* activity of inhibiting and/or killing a particular type of cancer to be indicative

that the compound has promise as a treatment for animals and humans afflicted with that

particular type of cancer. While *in vitro* results may not be a guarantee of *in vivo* efficacy, those

of skill in the relevant art view *in vitro* results as indeed indicative of the usefulness of the

compound *in vivo* for organisms having neoplasms/cancers, particularly but not necessarily those

types corresponding to the cell lines tested *in vitro*. The specification sets forth in Table 1 *in*

vitro test results for the claimed compounds against seven different cancer cell lines (leukemia,

pancreatic cancer, breast cancer, CNS-central nervous system- cancer, non-small cell lung

cancer, colon cancer and prostate cancer). The specification's teaching of these test results, along

with the teachings at pages 1-3 of the specification that these compounds show promising utility

in the treatment of cancer, would motivate one of skill in the art to reasonably believe that the

compounds would be useful if used *in vivo*.

The Examiner is correct that the pharmacological art involves screening *in vitro* and *in*

vivo to determine which compounds exhibit the desired pharmacological activities. However,

while there may be no absolute predictability that a compound that appears promising *in vitro*

will be useful *in vivo*, one of skill in the relevant art of cancer treatment research certainly looks

to *in vitro* results before even proceeding to *in vivo* tests; *in vitro* tests guide one of skill in the

art to pick and choose which compounds have a good chance of being useful *in vivo*, based upon

good activity *in vitro*. The fact that a compound shows good *in vitro* results against a particular

type of cancer is a very strong indication, even if not a guarantee, that the compound is likely to

also give good *in vivo* results against that type of cancer, i.e., it is well-accepted in the cancer

field that there is a strong correlation between *in vitro* activity and *in vivo* activity. The Office

Action provides no evidence to contradict this.

Moreover, despite the urging in the Office Action, it would not require undue

experimentation to translate these *in vitro* results to *in vivo* animal studies, and therafter to

translate successful *in vivo* animal studies to human studies. One would start by choosing a

compound that shows good *in vitro* activity against the particular cancer desired to be treated,

and then conducting *in vivo* tests, typically in small animals, particularly mammals such as mice,

to determine the potential toxicity to the animal. If toxicity is not found to be an issue, i.e.,

administering the compound to the study animal does not result in death and/or significant harm

to the animal, then one of skill would administer the compounds to animal models for the

particular cancer to be investigated (i.e., administer to a animal models which have been bred

with a predisposition for the cancer or in which the cancer has been induced or introduced).

After testing on small mammals, the compound would typically thereafter be

administered to a larger mammal, such as a dog or a primate, in order to better simulate the effect

that the compound would have on a human, both in terms of toxicity and in terms of efficacy for

the intended purpose.

Good results from animal studies would then lead one to conduct tests in human subjects

as is presently claimed.

Claims 3-4 stand provisionally rejected under the judicially created doctrine of

obviousness-type double patenting over claims 8 and 13 of Applicant's co-pending U.S.

application no. 11/071,994 (Chang et al.). Applicant will not address the substance of this

provisional rejection at this time, as it is not yet clear what claims will issue in the respective

applications. Applicant confirms that it will take appropriate action at such time as Chang's

claims or the above-identified application's claims are ready for issue.

In view of the foregoing, favorable consideration and allowance of all of the claims now

present in the application is most respectfully requested. The Examiner is invited to telephone

Applicant's undersigned representative, if this would in any way facilitate prosecution of the

application.

Dated: <u>February 4, 2008</u>   Respectfully submitted,

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